IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No. 23-975 (RGA) (SRF)
LIQUIDIA TECHNOLOGIES, INC.,	)	
Defendant.	)	

LETTER TO THE HONORABLE RICHARD G. ANDREWS

OF COUNSEL:

William C. Jackson
Katherine Cheng
GOODWIN PROCTER LLP
1900 N St. NW
Washington, DC 20036
(202) 346-4216

Eric T. Romeo
Louis L. Lobel
GOODWIN PROCTER LLP
100 Norther Avenue
Boston, MA 02210
(617) 570-1000

Douglas Carsten
Art Dykhuis
Katherine Pappas
MCDERMOTT WILL & EMERY LLP
18565 Jamboree Road, Suite 250
Irvine, CA 92615
(949) 851-0633

Adam W. Burrowbridge
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street
Washington, DC 20001-1531
(202) 756-8797

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Michael J. Flynn (#5333)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mflynn@morrisnichols.com

Attorneys for Plaintiff United Therapeutics Corporation

October 10, 2024

Dear Judge Andrews:

Plaintiff United Therapeutics Corporation ("UTC") writes in response to the Court's October 8, 2024, Order (D.I. 135). The Court ordered UTC to submit a letter "which includes the text of each asserted claim, and, for every time there is an 'a,' 'an,' or 'the' in connection with one of the six terms identified in the Joint Claim Construction Brief, exactly one construction for the 'a,' 'an,' or 'the.'" UTC hereby responds.

With its prior letter (D.I. 133), UTC intended to provide clarity on two issues: claim construction and the application of that construction. First, Liquidia's briefing only addressed "[a/the] patient." Thus, consistent with UTC's claim construction briefing and prior letter, UTC submits that "a patient" should be construed to mean "one or more patients." Following the specification and the Federal Circuit's general rule, "a," "an," and "the" should be construed as "one or more" in each of the six terms identified in the Joint Claim Construction Brief.

For clarity, the attached exhibit "includes the text of each asserted claim, and, for every time there is an 'a,' 'an,' or 'the' in connection with one of the six terms identified in the Joint Claim Construction Brief, exactly one construction for that 'a,' 'an,' or 'the.'" D.I. 135 at 3. To summarize, UTC proposes the following constructions:

	Disputed Terms from Joint Claim Construction Brief	**Construction**
1	"a" patient	"one or more"
2	"the" patient	"one or more"
3	"a" maximum tolerated dose	"one or more"
4	"a" single administration event	"one or more"
5	"the" administering	"one or more"
6	"the" single inhalation administration event	"one or more"

Second, UTC intended to assist the Court by explaining UTC's view of how these terms would be "applied" by the person of ordinary skill in the art in the context of infringement and invalidity. D.I. 133 at 1. Specifically, that person would understand that the claimed "maximum tolerated dose" is determined on a patient-by-patient basis because the claims and specification provide clear context describing the "maximum tolerated dose for the individual subject." '327 patent, 6:61-62; *see also id.*, 6:42-43 ("'Subject' and 'patient' may be used interchangeably").

As described in UTC's prior letter, the context can be relevant in the *application* of the claims. For example, if the factfinder was evaluating the application of the claims to a single patient, "a patient" would include that single patient, and "the patient" would likewise include that same single patient. *See Salazar v. AT&T Mobility LLC*, 64 F.4th 1311, 1315-16 (Fed. Cir. 2023). The skilled artisan would also understand that upon administration each patient has a single maximum tolerated dose. That remains true if the claims are "applied" to multiple patients, *i.e.*,

while *multiple* patients would implicate *multiple* maximum tolerated doses, the skilled artisan would understand that each individual patient has their own maximum tolerated dose. *See* '327 patent, 6:61-62. Because claim 1 is a "comprising" claim, the skilled artisan would understand that administering the claimed method to multiple patients is not outside the scope of the claims and that *each* "maximum tolerated dose" would still be determined on an "individual[ized]" basis.

In short, "a" maximum tolerated dose should be construed as "one or more" based on the clear context of the patent, which dictates (1) the individualized nature of "maximum tolerated dose," allowing only one "maximum tolerated dose" per patient, and (2) the comprising nature of the claims, which includes, but does not require, more than one maximum tolerated dose for multiple patients.

Respectfully,

Michael J. Flynn (#5333)
Counsel for United Therapeutics Corp.

cc: Clerk of the Court
All counsel of record

Exhibit 1 – Asserted Claims, Six Disputed Claim Terms from the Joint Claim Construction Brief, and Constructions

Claim	Text	Construction of Briefed "a" / "the" Terms
1.	A method of improving exercise capacity in **a patient** having pulmonary hypertension associated with interstitial lung disease, comprising administering by inhalation to **the patient** having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to **a maximum tolerated dose** of treprostinil or a pharmaceutically acceptable salt thereof in **a single administration event** that comprises at least 6 micrograms per breath.	**"a" patient** "*one or more*" **"the" patient** "*one or more*" **"a" maximum tolerated dose** "*one or more*" **"a" single administration event** "*one or more*"
2.	The method of claim 1, wherein said administering provides a statistically significant increase of a 6 minutes walk distance in **the patient** after 8 weeks, 12 weeks, or 16 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"
3.	The method of claim 1, wherein said administering increases a 6 minutes walk distance of **the patient** by at least 10 m after 8 weeks, 12 weeks, or 16 weeks of **the administering**	**"the" patient** "*one or more*" **"the" administering** "*one or more*"
4.	The method of claim 1, wherein said administering provides a statistically significant reduction of a plasma concentration of NT-proBNP in **the patient** after 8 weeks, 12 weeks, or 16 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"

Exhibit 1 – Asserted Claims, Six Disputed Claim Terms from the Joint Claim Construction Brief, and Constructions

Claim	Text	Construction of Briefed "a" / "the" Terms
5.	The method of claim 1, wherein said administering reduces a plasma concentration of NT-proBNP in **the patient** by at least 200 pg/ml after 8 weeks, 12 weeks, or 16 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"
6.	The method of claim 1, wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.	
7.	The method of claim 1, wherein said administering provides a statistically significant reduction of clinical worsening events due to the interstitial lung disease.	
8.	The method of claim 7, wherein the clinical worsening events comprise at least one of hospitalization for cardiopulmonary indication and a decrease in a 6-minute walk distance by more than 15% compared a baseline 6-minute walk distance prior to **the administering**.	**"the" administering** "*one or more*"
9.	The method of claim 1, wherein said administering provides a statistically significant improves of forced vital capacity (FVC) in **the patient** after 8 weeks, 12, weeks or 16 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"
10.	The method of claim 9, wherein said administering improves the forced vital capacity (FVC) in **the patient** by at least 20 ml after 8 weeks, 12 weeks, or 16 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"

Exhibit 1 – Asserted Claims, Six Disputed Claim Terms from the Joint Claim Construction Brief, and Constructions

Claim	Text	Construction of Briefed "a" / "the" Terms
11.	The method of claim 1, wherein said administering is performed by a pulsed inhalation device.	
14.	The method of claim 11, wherein the pulsed inhalation device is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.	
15.	The method of claim 1, wherein the effective amount of treprostinil or a pharmaceutically acceptable salt administered to **the patient** in **a single inhalation administration event** is from 15 µg to 100 µg.	**"the" patient** "*one or more*" **"the" single inhalation administration event** "*one or more*"
16.	The method of claim 15, wherein **the single inhalation administration event** does not exceed 15 breaths by **the patient**	**"the" patient** "*one or more*" **"the" single inhalation administration event** "*one or more*"
17.	The method of claim 1, wherein said administering increases a 6 minutes walk distance of **the patient** by at least 10 m after 8 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"
18.	The method of claim 1, wherein said administering increases a 6 minutes walk distance of **the patient** by at least 15 m after 12 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"

Exhibit 1 – Asserted Claims, Six Disputed Claim Terms from the Joint Claim Construction Brief, and Constructions

Claim	Text	Construction of Briefed "a" / "the" Terms
19.	The method of claim 1, wherein said administering increases a 6 minutes walk distance of **the patient** by at least 15 m after 16 weeks of **the administering**.	**"the" patient** "*one or more*" **"the" administering** "*one or more*"